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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,153	05/14/2001	Robert E. Reiter	30435.69USD1	1003

26941 7590 08/28/2002

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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 08/28/2002

109

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,153

Applicant(s)

REITER ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 53-69 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53 and 54 is/are rejected.
- 7) ☒ Claim(s) 55-69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)


- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 53-69, in Paper No. 13 is acknowledged. The traversal is on the ground(s) that "The Patent Office has not demonstrated a serious burden for searching the art" and "each of the claims are Groups I and II are classified in class 530". This is not persuasive. Applicant has provided no evidence to establish why the requirement for restriction is improper. Although both groups I and III are classified in the same class, they are classified in different subclasses. As to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is made **FINAL**.
2. Claim 1 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 9.
3. Claims 53-69 are under examination.

Specification

4. The disclosure is objected to because of the following informalities:
- 

a. The first line of the specification should be updated to indicate the U.S. Patent numbers for applications 09/251835, 09/203939, 09/038,261, and 09/318503.

b. The Brief Description of the Drawings, pages 6-18, is incomplete as it lacks a separate description for the Figures 10A-C, 14A-C, 16A-B, 62A-D. The Brief Description of the Drawings need to be amended so that Figures recite separate descriptions for each view that match the labels for the Drawings. Also any reference to the figures in the specification needs to be amended accordingly.

c. The address of the ATCC on page 28, line 3 needs to be updated. The new address is: 10801 University Boulevard, Manassas, VA 20110-2209.

d. The specification needs to have a SEQ ID NO for every sequence that is encompassed by the sequence rules. For example the sequences listed on page 113, lines 20 and 21 do not have SEQ ID Nos. Applicant is directed to 37 CFR 1.821(d).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 54 recites "the PSA protein fragment of claim 53 consisting of amino acids residues 1 through 123 as described in SEQ ID NO:2. The claim is indefinite because the PSCA protein of SEQ ID NO:2 only has 1-123 amino acids, so it is unclear what protein fragment is claimed. Amending the claim by removing "fragment of claim 53" would obviate this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim recites a prostate stem cell antigen protein fragment which induces an immune response in a subject wherein the fragment is a portion of the PSCA protein.

The specification teaches the human PSCA protein (SEQ ID NO:2) and the murine PSCA protein (SEQ ID NO:4). The specification describes the PSCA protein as

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"includes all naturally occurring allelic variants, isoforms, and precursors of human" and murine PSCA (see page 20, lines 16-29).

The general knowledge in the art concerning variants does not provide any indication of how the structure of one variant is representative of unknown variants. Reiger et al. (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlag, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:2 and 4 the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. The specification fails to provide any teachings as to how the structure of this protein relates or contributes to its function/activity. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of two sequences is insufficient to describe the genus.

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed and one skilled in the art can reasonably conclude that applicant did not have possession of the claimed invention at the time of filing. It is not at all clear that the two species disclosed in the specification would be considered a representative number of

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species of all PSCA proteins by one of skill in the art. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 53 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young (U.S. Patent 5,856,136, filed 7/3/96).

The claims recite a prostate stem cell antigen protein fragment which induces an immune response in a subject wherein the fragment comprises a portion of the PSCA protein and consists of amino acids 1 to 123 of SEQ ID NO:2.

Au-Young teach the SCAH-2 protein SEQ ID NO:2 (see column 2, lines 14-16 and 44-50, column 14, lines 22-32). Au-Young also teach antigenic peptides of the protein (see columns 13-14). The SCAH-2 protein of AU-Young is the identical protein as PSCA in the instant invention (see SEQ ID NO:2 in Au-Young patent as compared to SEQ ID NO:2 in the instant application) except at amino acid 94. (A sequence

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alignment for SEQ ID NO:2 of Au-Young and SEQ ID NO:2 of the instant application is attached to the back of this Office Action. "Qy" is the instant application SEQ ID NO:2 and "Db" is Au-Young SEQ ID NO:2) SEQ ID NO:4 of Au-Young is the DNA that encodes SEQ ID NO:2 of Au-Young. At nucleotide 296 the nucleotide in SEQ ID NO:4 is a "S". Standard IUB meaning for this convention is that this nucleotide is a "G" or a "C". The codon for the amino acid sequence of SEQ ID NO:2 of Au-Young at position 94 is listed as a "X" but if nucleotide 294 is a "C" then the codon would code for Alanine and if the nucleotide at 294 is a "G" this would be a glycine (see the genetic code at page 41 of Watson et al (Recombinant DNA, Scientific American Books, 1992). Thus, Au-Young teach a sequence identical to SEQ ID NO:2 of the instant application.

Conclusion

11. No claim is allowed. Claims 55-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or fairly suggest protein fragments with the defined amino acid residues as recited in claims 55-69.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00

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am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.

SOFTWARE: FastSEQ Version 1.5
 CURRENT APPLICATION DATA:
 APPLICATION NUMBER: US/08/675,508
 FILING DATE: Filed Herewith
 ATTORNEY/AGENT INFORMATION:
 NAME: Billings, Lucy J.
 REGISTRATION NUMBER: 36,749
 REFERENCE/DOCKET NUMBER: PF-0066 US
 TELECOMMUNICATION INFORMATION:
 TELEPHONE: 415-855-0555
 TELEFAX: 415-845-4166
 INFORMATION FOR SEQ ID NO: 2:
 SEQUENCE CHARACTERISTICS:
 LENGTH: 123 amino acids
 TYPE: amino acid
 STRANDEDNESS: single
 TOPOLOGY: linear
 MOLECULE TYPE: peptide
 IMMEDIATE SOURCE:
 LIBRARY: SCAH-2
 CLONE:
 US-08-675-508-2

Query Match 99.4%; Score 645; DB 2; Length 123;
 Best Local Similarity 99.2%; Pred. No. 1.le-67;
 Matches 122; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

QY	1	MKAVLLALLMAGLALQPGTALLCYSCKAQVSNEDCLOVENC	TOLGEOCWTARIRAVGLLT	60
Db	1	MKAVLLALLMAGLALQPGTALLCYSCKAQVSNEDCLOVENC	TOLGEOCWTARIRAVGLLT	60
QY	61	VISKGSILNCVDDSDDYVVGKKNITCCD	TDLCNAGSAHALQPAATLALPALGLLWGP	120
Db	61	VISKGSILNCVDDSDDYVVGKKNITCCD	TDLCNAGSAHALQPAATLALPALGLLWGP	120
QY	121	GQL	123	
Db	121	GQL	123	

RESULT 9
 US-08-675-508-2
 Sequence 2, Application US/08675508
 Patent No. 5856136
 GENERAL INFORMATION:
 APPLICANT: Au-Young, Janice
 TITLE OF INVENTION: NOVEL HUMAN STEM CELL ANTIGENS
 NUMBER OF SEQUENCES: 26
 CORRESPONDENCE ADDRESS:
 ADDRESSEE: Incyte Pharmaceuticals, Inc.
 STREET: 3174 Porter Drive
 CITY: Palo Alto
 STATE: CA
 COUNTRY: U.S.
 ZIP: 94304
 COMPUTER READABLE FORM:
 MEDIUM TYPE: Diskette
 COMPUTER: IBM Compatible
 OPERATING SYSTEM: DOS